

Regimen Monograph

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A - Regimen Name

TMXF Regimen

Tamoxifen

Disease Site Breast**Intent** Adjuvant**Regimen Category** **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses Adjuvant treatment of breast cancer (estrogen receptor positive tumours) in women**Supplementary Public Funding** [tamoxifen](#)
ODB - General Benefit (tamoxifen) ([ODB Formulary](#))[back to top](#)

B - Drug Regimen[tamoxifen](#)

20 mg

PO

Daily

(Outpatient prescription in multiples of 10 and 20 mg tablets)

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Premenopausal patients: Treatment for 5 to 10 years

Postmenopausal patients: Treatment for 5 to 10 years, or tamoxifen for 2-5 years, followed by aromatase inhibitor for 3-5 years

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Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

See appendix 6 for general recommendations.

Dosage with toxicity

Toxicity	Action
Severe estrogen depletion symptoms	Consider short drug holiday and rechallenge
Arterial/Venous thromboembolism	Discontinue

Severe depression	Discontinue
Pancreatitis, pneumonitis, hepatotoxicity, severe hypercalcemia	Discontinue
Cataracts, retinopathy, corneal changes, severe myalgia	Consider discontinuing
Severe skin symptoms, porphyria cutanea tarda, cutaneous lupus erythematosus	Discontinue
Microvascular breast reconstruction	Consider temporary hold

Hepatic Impairment

Adjustment required, no details found

Renal Impairment

No adjustment required

Dosage in the Elderly

No adjustment required.

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F - Adverse Effects

Refer to [tamoxifen](#) drug monograph(s) for additional details of adverse effects

Most Common Side Effects (>10%)	Less Common Side Effects, but may be Severe or Life-Threatening
<ul style="list-style-type: none"> • Estrogen withdrawal symptoms • Nausea, vomiting • Rash (may be severe) 	<ul style="list-style-type: none"> • Hypersensitivity • Arterial thromboembolism • Venous thromboembolism

- | | |
|---|---|
| <ul style="list-style-type: none"> • Fluid retention • Vaginal discharge, bleeding • Fatigue | <ul style="list-style-type: none"> • Ocular disorders (retinopathy, cataracts, optic neuritis) • Endometrial hyperplasia, polyps • Pancreatitis • Pneumonitis • Secondary malignancies (including uterine sarcoma/endometrial cancer) • Tumour flare (including hypercalcemia) • Porphyria, cutaneous lupus erythematosus, cutaneous vasculitis • ↑ LFTs • Radiation recall reaction |
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G - Interactions

Refer to [tamoxifen](#) drug monograph(s) for additional details

- Avoid concomitant use with potent CYP2D6 inhibitors (e.g. fluoxetine, paroxetine, quinidine, pimozide, perphenazine)
- Caution with the use of moderate CYP2D6 inhibitors (e.g. desipramine, haloperidol, citalopram, sertraline, hydroxyzine, amlodipine) and consider alternative drug options
- Do not coadminister with anastrozole or letrozole
- Exercise caution when given with CYP3A4 inducers
- May significantly increase anticoagulant effect. Monitor prothrombin time; adjust anticoagulant dose as required
- Avoid concomitant use with drugs that prolong the QT interval

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H - Drug Administration and Special Precautions

Refer to [tamoxifen](#) drug monograph(s) for additional details

Administration

- Oral self-administration; drug available by outpatient prescription.
- Swallow whole with a glass of water, with or without food.
- Do not crush or chew the tablets.
- Take the dose at about the same time each day.

Contraindications/Precautions

- Patients with hypersensitivity to tamoxifen or any of its components.
- Use with extreme caution in patients with a history of significant thromboembolic disease.
- Some brands of tamoxifen contain lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.
- Use with caution in patients with pre-existing myelosuppression or depression.
- Consider temporary hold in patients undergoing delayed microvascular breast reconstruction.
- Tiredness and weakness have been reported. Caution when driving and operating machinery while such symptoms persist.

Pregnancy / Lactation

- Tamoxifen is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment and for **9 months** after the last dose.
- Breastfeeding is not recommended.
- Fertility effects are unknown.

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Calcium, in patients with extensive bone metastases; for first few weeks then periodic
- Clinical assessment of toxicity - vaginal bleeding, ocular, thromboembolism, myalgia, tumour flare, GI and pulmonary effects, rash, etc.
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

Suggested Clinical Monitoring

- CBC; Periodic
- Triglycerides and cholesterol in patients with pre-existing hyperlipidemia

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Anon, Adjuvant tamoxifen in the management of operable breast cancer: The Scottish Trial. Lancet, 1987; 2(8552): 171-5.

Controlled trial of tamoxifen as a single adjuvant agent in the management of early breast cancer. Nolvadex Adjuvant Trial Organisation. Br J Cancer 1988;57(6):608-11.

Fisher B et al. Treatment of primary breast cancer with chemotherapy and tamoxifen. N Engl J Med 1981;305(1):1-6.

Tamoxifen for early breast cancer: an overview of the random trials. Early Breast Cancer Trialists' Collaborative Group. Lancet 1998;351(9114):1451-67.

PEBC Advice Documents or Guidelines

- [Optimal Systemic Therapy for Early Female Breast Cancer](#)

June 2022 Updated Cycle frequency and Pregnancy/lactation sections

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L - Other Notes

Due to low drug costs, it is advisable to prescribe in lots of 3 months (or longer) once treatment is established. This will reduce cost to the patient or prescription plan.

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an “as-is” basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information’s quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the “Formulary”) is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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